510(k) Summary
for the InterForm Interbody Cage System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the InterForm Interbody Cage System

1. GENERAL INFORMATION

Date Prepared: April 16, 2013

Trade Name: InterForm Interbody Cage System

Common Name: intervertebral body fusion device

Classification Name: Intervertebral body fusion device – lumbar

Class: II

Product Code: MAX

CFR section: 21 CFR section 888.3080

Device panel: Orthopedic

Legally Marketed Predicate Device:
Spinal Elements, Lucent Straight Interbody Cage (K071724/K081968)
DePuy, Brantigan I/F CAGE (P960025)
SEASPINE, Pacifica Cage (K082310)
DiFusion Technologies, XIPHOS Interbody Fusion System (K100042)
Synthes T-PAL (K100089)
Nuvasive CoRoent XL (K071795/ K081611)
Medtronic Capstone (K073291)
Synthes OPAL (K072791)
GS Medical ANYPLUS (K100516)
Medtronic Boomerang (K023570)
Synthes Oracle (K062933)
Spinal USA ShurFit (K092193)
Amedica Valeo (K091278)

Submitter:
Next OrthoSurgical
3270 Corporate View, Suite A
Vista CA. 92081
760-295-3600 Tele
760-295-3610 Fax

Contact:
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199 Tele
512-692-3699 Fax
e-mail: jdwebb@orthomedix.net

2. DEVICE DESCRIPTION

The InterForm PLIF Interbody Fusion Implants consists of cage footprint widths of 9, 11, 13mm , lengths of 20, 22, 24, 26, 28, 30mm, ranging in height from 7mm to 14mm with lordosis of 5°, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. These implants are manufactured from implant grade polyetheretherketone (PEEK). The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The InterForm PLIF Interbody Fusion devices are intended to be implant via an open or minimally invasive, posterior approach and used with supplemental fixation and autogenous bone graft.

The InterForm TLIF Interbody Fusion Implants consists of cage footprints widths of 9, 11, 13mm , lengths of 22, 24, 26, 28, 30, 32mm, ranging in height from 7mm to 14mm with lordosis of 5°, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. These implants are manufactured from implant grade polyetheretherketone (PEEK). The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The InterForm TLIF Interbody Fusion devices are intended to be implant via an open or minimally invasive, transforaminal approach and used with supplemental fixation and autogenous bone graft.

The InterForm OTLIF Interbody Fusion Implants consists of cage footprint widths of 9, 11, 13mm , lengths of 20, 22, 24, 26, 28, 30, 32, 34mm, ranging in height from 7mm to 14mm with lordosis of 0°, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. These implants are manufactured from implant grade polyetheretherketone (PEEK). The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The InterForm OTLIF Interbody Fusion devices are intended to be implant via an open or minimally invasive, posterior or transforaminal approach and used with supplemental fixation and autogenous bone graft.

The InterForm LLIF Interbody Fusion Implants consists of cage footprint widths of 18, 20, 22, 24mm, lengths of 40, 45, 50, 55, 60mm, ranging in height from 8mm to 18mm with lordosis of 0° or 7°, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. These implants are manufactured from implant grade polyetheretherketone (PEEK). The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The InterForm LLIF Interbody Fusion devices are intended to be implant via a lateral approach and used with supplemental fixation and autogenous bone graft.

The InterForm ALIF Interbody Fusion Implants consists of cage footprints of 30x24mm, 36x28mm, and 39x30mm (DxW), ranging in height from 10mm to 20mm with lordosis of 0°, 7° or 12° which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. These implants are manufactured from implant grade polyetheretherketone (PEEK). The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The InterForm ALIF Interbody Fusion devices are intended to be implant via an open or minimally invasive, anterior approach and used with supplemental fixation and autogenous bone graft.

All implants are packaged non-sterile to be sterilized at the hospital.

Materials:

PEEK Optima LT1 conforming to ASTM F2026.
Unalloyed tantalum conforming to ASTM F560.

Function:

Maintain adequate disc space until fusion occurs.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The InterForm Interbody Cage System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

When used as an intervertebral body fusion device, the InterForm Lumbar Interbody Cage System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft to facilitate fusion. Additionally, the InterForm Lumbar Interbody Cage System is intended for use with supplemental spinal fixation systems cleared for use in the lumbar spine. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Static and dynamic compression per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

The results of this testing indicate that the InterForm Interbody Cage System is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Next OrthoSurgical considers the InterForm Interbody Cage System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2013

Next OrthoSurgical
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K131082
Trade/Device Name: InterForm Lumbar Interbody Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 22, 2013
Received: July 31, 2013

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K131082

Device Name: InterForm Lumbar Interbody Cage System

Indications for Use:

When used as an intervertebral body fusion device, the InterForm Lumbar Interbody Cage System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft to facilitate fusion. Additionally, the InterForm Lumbar Interbody Cage System is intended for use with supplemental spinal fixation systems cleared for use in the lumbar spine. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices